



01-26-04

Express Mail No.: EV335858305US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Oshlack et al. Confirmation No.: 3622
Serial No.: 10/664,602 Art Unit: 1645
Filed: September 16, 2003 Examiner: To Be Assigned
For: MELT-EXTRUDED ORALLY ADMINISTRABLE OPIOID FORMULATIONS Attorney Docket No.: 6750-244-999

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:
 - 1a. A list of all patents, publications, applications, or other information submitted for consideration by the office (References A01-A125; B01-B131; and C01-C61).
 - 1b. A legible copy of References B127-B131.
2. This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the mailing of a first Office action on the merits.
3. This application is a continuation application under 37 C.F.R. §1.53(b) or (d).
 - 3a. Copies of References **A01-A125**; **B01-B126** and **C01-C61** listed on Form PTO-1449 were previously cited and submitted in prior application Serial No. 09/777,616, filed on February 6, 2001, of which this application claims priority under 35 U.S.C. §120, and are not being submitted pursuant to 37 C.F.R. §1.98(d).
 - 3b. Copies of References **B127-B131** listed on Form PTO-1449 were not previously cited in prior application Serial No. 09/777,616, filed on February 6, 2001, and are provided herewith.
9. The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Deposit Account No. 16-1150.
10. No admission is made that the information cited in this Statement is, or is considered to be, material to patentability nor a representation that a search has been made (other than a search

report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Date: January 22, 2004

Respectfully submitted,

Gidon D. Stern Reg. No. 27,469
by Brian C. Remy Reg. No. 48,176 27,469

Gidon D. Stern (Reg. No.)

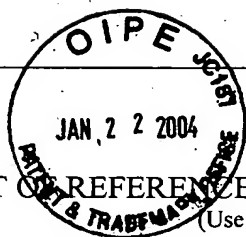
JONES DAY

222 East 41st Street

New York, New York 10017

(212) 326-3939

Enclosures



LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY DOCKET NO.

6750-244-999

APPLICATION NO

10/664,602

APPLICANT

Oshlack et al.

FILING DATE

September 16, 2003

GROUP

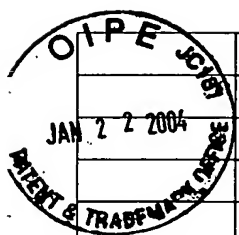
1645

U.S. PATENT DOCUMENTS

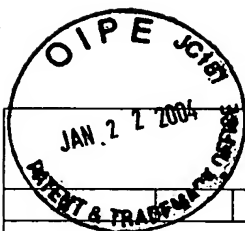
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	Re. 33,093	10/17/89	Schiraldi et al.	424	676	
	A02	2,738,303	3/13/56	Blythe et al.	167	82	
	A03	3,065,143	11/20/62	Christenson et al.	167	82	
	A04	3,652,589	3/28/72	Flick et al.	260	326.5M	
	A05	3,714,350	1/30/73	Gough	424	203	
	A06	3,830,934	8/20/74	Flick et al.	424	330	
	A07	3,845,770	11/5/74	Theeuwes et al.	128	260	
	A08	3,880,991	4/29/75	Yolles	424	22	
	A09	3,950,508	4/13/76	Mony et al.	424	19	
	A10	3,965,256	6/22/76	Leslie	424	22	
	A11	3,974,157	8/10/76	Shetty et al.	260	247.2B	
	A12	4,013,784	3/22/77	Speiser	424	19	
	A13	4,076,798	2/28/78	Casey et al.	424	22	
	A14	4,132,753	1/2/79	Blichare et al.	264	25	
	A15	4,173,417	11/6/79	Kruder	366	89	
	A16	4,230,687	10/28/80	Sair et al.	424	22	
	A17	4,259,314	3/31/81	Lowey	424	19	
	A18	4,265,875	5/5/81	Byrne et al.	424	19	
	A19	4,292,300	9/29/81	Byrne et al.	424	19	
	A20	4,310,483	1/12/82	Dorfel et al.	264	117	
	A21	4,343,789	8/10/82	Kawata et al.	424	78	
	A22	4,344,431	8/17/82	Yolles	128	260	
	A23	4,346,709	8/31/82	Schmitt	128	260	
	A24	4,366,172	12/28/82	Lednicer	424	330	
	A25	4,374,082	2/15/83	Hochschild	264	129	
	A26	4,380,534	4/19/83	Fukui et al.	424	38	
	A27	4,389,393	6/21/83	Schor et al.	424	19	
	A28	4,406,883	9/27/83	Byrne et al.	424	80	
	A29	4,421,736	12/20/83	Walters et al.	424	19	
	A30	4,483,847	11/20/84	Augart	424	22	
	A31	4,533,562	8/6/85	Ikegami et al.	427	3	
	A32	4,613,619	9/23/86	Sleigh et al.	514	546	
	A33	4,621,114	11/4/86	Watanabe	524	451	
	A34	4,649,042	3/10/87	Davis et al.	424	438	
	A35	4,720,384	1/19/88	DiLuccio et al.	424	78	
	A36	4,764,378	8/16/88	Keith et al.	424	435	



A37	4,778,676	10/18/88	Yang et al.	424	79	
A38	4,801,458	1/31/89	Hidaka et al.	424	443	
A39	4,801,460	1/31/89	Goertz et al.	424	465	
A40	4,806,337	2/21/89	Snipes et al.	71	65	
A41	4,818,450	4/4/89	Hall et al.	264	39	
A42	4,828,836	5/9/89	Elger et al.	424	419	
A43	4,834,984	5/30/89	Goldie et al.	424	488	
A44	4,842,761	6/27/89	Rutherford	252	90	
A45	4,844,907	7/4/89	Elger et al.	424	465	
A46	4,844,909	7/4/89	Goldie et al.	424	480	
A47	4,861,598	8/29/89	Oshlack	424	468	
A48	4,879,108	11/7/89	Yang et al.	424	440	
A49	4,880,585	11/14/89	Klimesch et al.	264	141	
A50	4,880,830	11/14/89	Rhodes	424	470	
A51	4,882,151	11/21/89	Yang et al.	424	440	
A52	4,882,152	11/21/89	Yang et al.	424	440	
A53	4,882,153	11/21/89	Yang et al.	424	440	
A54	4,882,155	11/21/89	Yang et al.	424	440	
A55	4,882,156	11/21/89	Yang et al.	424	440	
A56	4,882,157	11/21/89	Yang et al.	424	440	
A57	4,882,159	11/21/89	Yang et al.	424	440	
A58	4,882,167	11/21/89	Jang	424	468	
A59	4,894,234	1/16/90	Sharma et al.	424	440	
A60	4,917,899	4/17/90	Geoghegan et al.	424	461	
A61	4,925,675	5/15/90	Giannini et al.	424	78	
A62	4,935,246	6/19/90	Ahrens	424	490	
A63	4,957,681	9/18/90	Klimesch et al.	264	211.23	
A64	4,959,208	9/25/90	Chakrabarti et al.	414	78	
A65	4,967,486	11/6/90	Doelling	34	1	
A66	4,970,075	11/13/90	Oshlack	424	451	
A67	4,987,136	1/22/91	Kreek et al.	514		
A68	4,990,341	2/5/91	Goldie et al.	424	484	
A69	4,992,100	2/12/91	Koepff et al.	106	125S	
A70	4,994,227	2/19/91	Dietz et al.	264	328.16	
A71	5,007,790	4/16/91	Shell	424	451	
A72	5,013,306	5/7/91	Solomon et al.	604	265	
A73	5,023,089	6/11/91	Sakamoto et al.	424	502	
A74	5,026,560	6/25/91	Makino et al.	424	494	
A75	5,030,400	7/9/91	Danielson et al.	264	101	
A76	5,035,509	7/30/91	Kruder	366	89	
A77	5,049,394	9/17/91	Howard et al.	424	490	
A78	5,055,307	10/8/91	Isuru et al.	424	493	
A79	5,073,379	12/17/91	Klimesch et al.	424	467	
A80	5,102,668	4/7/92	Eichel et al.	424	490	
A81	5,126,145	6/30/92	Evenstad et al.	424	465	

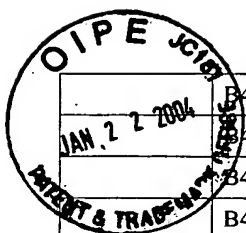


A82	5,132,142	7/21/92	Jones et al.	427	196	
A83	5,133,974	7/28/92	Paradissis et al.	424	480	
A84	5,162,117	11/10/92	Stupak et al.	424	475	
A85	5,165,952	11/24/92	Solomon et al.	427	2	
A86	5,167,964	12/1/92	Muhammed et al.	424	482	
A87	5,169,645	12/8/92	Shukla et al.	424	499	
A88	5,178,868	1/12/93	Malmqvist-Granlund et al.	424	490	
A89	5,183,690	2/2/93	Carr et al.	427	213.31	
A90	5,196,203	3/23/93	Boehm	424	490	
A91	5,202,128	4/13/93	Morella et al.	424	469	
A92	5,204,119	4/20/93	Shiobara et al.	424	489	
A93	5,229,148	7/20/93	Copper	426	5	
A94	5,234,697	8/10/93	Sipos	424	490	
A95	5,240,400	8/31/93	Fujimoto et al.	425	310	
A96	5,262,172	11/16/93	Sipos	424	490	
A97	5,266,331	11/30/93	Oshlack et al.	424	468	
A98	5,271,934	12/21/93	Goldberg et al.	424	401	
A99	5,273,758	12/28/93	Royce	424	465	
A100	5,283,065	2/1/94	Doyon et al.	424	467	
A101	5,290,560	3/1/94	Autant et al.	424	438	
A102	5,292,461	3/8/94	Juch et al.	264	37	
A103	5,296,266	3/22/94	Kunugi et al.	427	213	
A104	5,300,300	4/5/94	Egidio et al.	424	456	
A105	5,340,581	8/23/94	Tseng et al.	424	401	
A106	5,350,584	9/27/94	McClelland et al.	424	501	
A107	5,354,856	10/11/94	Kawashima et al.	536	127	
A108	5,356,635	10/18/94	Raman et al.	424	484	
A109	5,378,462	1/3/95	Boedecker et al.	424	94.29	
A110	5,380,535	1/10/95	Geyer et al.	424	484	
A111	5,395,626	3/7/95	Kotwal et al.	424	472	
A112	5,403,593	4/4/95	Royce	424	489	
A113	5,443,846	8/22/95	Yoshioka et al.	424	498	
A114	5,451,424	9/19/95	Solomon et al.	427	2.1	
A115	5,453,283	9/26/95	Munch et al.	424	489	
A116	5,456,923	10/10/95	Nakamichi et al.	424	489	
A117	5,472,710	12/5/95	Klokkers-Bethke et al.	424	468	
A118	5,476,528	12/19/95	Trimm et al.	71	21	
A119	5,478,577	12/26/95	Sackler et al.	424	489	
A120	5,510,114	4/23/96	Borella et al.	424	452	
A121	5,516,205	5/14/96	Oda et al.	366	75	
A122	5,552,159	9/3/96	Mueller et al.	424	464	
A123	5,567,439	10/22/96	Myers et al.	424	486	
A124	5,700,410	12/23/97	Nakamichi et al	264	122	
A125	5,958,452	9/28/99	Oshlack	424	457	



FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B01	EP 0 021 129 B2	1/17/81	EP				
	B02	EP 0 032 004 A2	7/15/81	EP				
	B03	EP 0 043 254 B1	1/6/82	EP				
	B04	EP 0 068 450 B1	1/5/83	EP				
	B05	EP 0 097 523 A2	1/4/84	EP				
	B06	EP 0 108 218 A2	5/16/84	EP				
	B07	EP 0 147 780 A2	7/10/85	EP				
	B08	EP 0 152 379 A2	8/21/85	EP				
	B09	EP 0 189 861 A2	8/6/86	EP				
	B10	EP 0 204 596 A1	12/10/86	EP				
	B11	EP 0 205 282 B1	12/17/86	EP				
	B12	EP 0 208 144 A1	1/14/87	EP				
	B13	EP 0 214 735 A1	3/18/87	EP				
	B14	EP 0 239 983 B1	10/7/87	EP				
	B15	EP 0 240 904 B1	10/14/87	EP				
	B16	EP 0 240 906 A2	10/14/87	EP				
	B17	EP 0 241 615 B1	10/21/87	EP				
	B18	EP 0 248 548 A2	12/9/87	EP				
	B19	EP 0 249 347 A2	12/16/87	EP				
	B20	EP 0 249 347 B1	12/16/87	EP				
	B21	EP 0 251 459 A2	7/1/88	EP				
	B22	EP 0 253 104 A1	1/20/88	EP				
	B23	EP 0 254 978 A1	2/3/88	EP				
	B24	EP 0 256 127 B1	2/24/88	EP				
	B25	EP 0 267 702 A2	5/18/88	EP				
	B26	EP 0 271 193 A2	6/15/88	EP				
	B27	EP 0 275 834 A1	7/27/88	EP				
	B28	EP 0 295 212 A2	12/14/88	EP				
	B29	EP 0 298 355 B1	1/11/89	EP				
	B30	EP 0 300 897 A2	1/25/89	EP				
	B31	EP 0 320 480 B1	6/14/89	EP				
	B32	EP 0 327 295 A2	8/9/89	EP				
	B33	EP 0 337 256 A2	10/18/89	EP				
	B34	EP 0 338 383 B1	10/25/89	EP				
	B35	EP 0 351 580 A2	1/24/90	EP				
	B36	EP 0 354 345 A2	2/14/90	EP				
	B37	EP 0 358 105 A2	03/14/90	EP				
	B38	EP 0 358 107 A2	03/14/90	EP				
	B39	EP 0 361 680 B1	4/4/90	EP				
	B40	EP 0 361 910 A1	4/4/90	EP				
	B41	EP 0 368 247 A2	5/16/90	EP				
	B42	EP 0 375 063 A1	6/27/90	EP				



B43	EP 0 377 517 A2	7/11/90	EP				
B44	EP 0 377 518 A2	7/11/90	EP				
B45	EP 0 415 693 A1	3/6/91	EP				
B46	EP 0 430 287 B1	6/5/91	EP				
B47	EP 0 436 786 B1	7/17/91	EP				
B48	EP 0 452 145 A2	10/16/91	EP				
B49	EP 0 463 833 A2	1/2/92	EP				
B50	EP 0 465 338	1/8/92	EP				
B51	EP 0 481 600 A2	4/22/92	EPO				
B52	EP 0 491 238 B1	6/24/92	EP				
B53	EP 0 526 862 A1	2/10/93	EP				
B54	EP 0 529 396	3/3/93	EP				
B55	EP 0 531 611 A1	3/17/93	EP				
B56	EP 0 533 297 A1	3/24/93	EP				
B57	EP 0 534 628 A1	3/31/93	EP				
B58	EP 0 535 841 A1	4/7/93	EP				
B59	EP 0 544 144 A1	6/2/93	EP				
B60	EP 0 546 676 A1	6/16/93	EP				
B61	EP 0 574 894 A1	12/22/93	EP				
B62	EP 0 580 860 A1	2/2/94	EP				
B63	EP 0 582 380 A1	2/9/94	EP				
B64	EP 0 595 311 A1	5/4/94	EP				
B65	EP 0 609 961 A1	8/10/94	EP				
B66	EP 0 624 366	11/17/94	EP				
B67	EP 0 624 366 B1	11/17/94	EP				
B68	EP 0 636 370 A1	2/1/95	EP				
B69	EP 0 642 788 A2	3/15/95	EP				
B70	EP 0 665 010 A1	8/2/95	EP				
B71	WO 91/04015	4/4/91	PCT				
B72	WO 91/19484	12/26/91	PCT				
B73	WO 91/19485	12/26/91	PCT				
B74	WO 92/01446	2/6/92	PCT				
B75	WO 92/02209	2/20/92	PCT				
B76	WO 92/05774	4/16/92	PCT				
B77	WO 92/06679	4/30/92	PCT				
B78	WO 92/18106	10/29/92	PCT				
B79	WO 92/22283	12/23/92	PCT				
B80	WO 93/00063	01/07/93	PCT				
B81	WO 93/00076	1/7/93	PCT				
B82	WO 93/04675	3/18/83	PCT				
B83	WO 93/07859	04/29/93	PCT				
B84	WO 93/07861	4/29/93	PCT				
B85	WO 93/10765	06/10/93	PCT				
B86	WO 93/17667	9/16/93	PCT				
B87	WO 93/18753	9/30/93	PCT				
B88	WO 93/24110	12/09/93	PCT				



B89	WO 94/03160	2/17/94	PCT				
B90	WO 94/03161	2/17/94	PCT				
B91	WO 94/05262	3/17/94	PCT				
B92	WO 94/08568	04/28/94	PCT				
B93	WO 94/10759	5/11/94	PCT (EP 0 667065 A1)				
B94	WO 94/22431	10/13/94	PCT				
B95	WO 94/23698	10/27/94	PCT				
B96	WO 94/23700	10/27/94	PCT				
B97	WO 95/14460	6/1/95	PCT				
B98	AU-B-57224/86	11/13/86	Australia				
B99	AU-B-89760/91	6/18/92	Australia				
B100	CA 2 082 573	5/24/93	Canada				
B101	CA 2,131,350	3/4/95	Canada				
B102	CA 2,150,304	12/1/95	Canada				
B103	FR 2 273 512	1/2/76	France				
B104	FR 2 273 584	1/2/76	France				
B105	FR 2 642 420	3/31/90	France				
B106	DT 2439538 A1	3/4/76	Germany				
B107	DE 3602360 A1	7/30/87	Germany				
B108	DE 3602370 A1	8/6/87	Germany				
B109	DE 3623193 A1	1/14/88	Germany				
B110	DE 4329794 A1	3/9/95	Germany				
B111	JP 2-223513	9/5/90	Japan				
B112	JP 2-223533	9/5/90	Japan				
B113	JP 5-257315	10/8/93	Japan				
B114	GB 997,399	7/7/1965	United Kingdom				
B115	GB 1405 088	9/3/75	United Kingdom				
B116	GB 1504 553	3/22/78	United Kingdom				
B117	GB 1513 166	6/7/78	United Kingdom				
B118	GB 2030 861 A	4/16/80	United Kingdom				
B119	GB 2053 681 A	2/11/81	United Kingdom				
B120	GB 2111 386 A	7/6/83	United Kingdom				
B121	GB 2117 239 A	10/12/83	United Kingdom				
B122	GB 2196 848 A	5/11/88	United Kingdom				
B123	GB 2207 355 A	2/1/89	United Kingdom				
B124	GB 2246 514 A	2/5/92	United Kingdom				
B125	GB 2281 204 A	3/1/95	United Kingdom				
B126	GB 2284 760 A	6/21/95	United Kingdom				
B127	WO 03/004029 A1	1/16/2003	PCT				
B128	WO 03/004030 A1	1/16/2003	PCT				
B129	WO 03/004031 A1	1/16/2003	PCT				
B130	WO 03/004032 A1	1/16/2003	PCT				
B131	WO 03/004033 A1	1/16/2003	PCT				



OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C01	Abstract No. 2-223533 "Agent with Release-Controlled Matrix"
C02	Abstract of EP 0208144, published 1-14-87
C03	Abstract of EP 358 107, published 3/14/1990
C04	Abstract of DE 2553026 (1976)
C05	Abstract of JP 62040277, published 2/21/1987
C06	Abstract of JP 58109411, published 6/29/1983
C07	CA 101:60081
C08	CA 112:75438
C09	CA 113:218240
C10	CA 113:98975
C11	CA 114:30199
C12	CA 115:177364
C13	CA 74:67660
C14	Alderman, "A Review of Cellulose Ethers in Hydrophilic Matrices for Oral Controlled-Release Dosage Forms," Int. J. Pharm. Tech. and Prod. Mft., 5(3), pp. 1-9 (1984)
C15	Aqualon Technical Information Bulletin, VC-585, 1991
C16	Baveja et al., "Release characteristics of some bronchodilators ...", Int. J. Pharmaceutics, 41, pp. 55-62 (1988)
C17	Cheong et al., "Relationship Between Polymer Viscosity and Drug Release from a Matrix System," Pharm. Res 9 (11), pp. 1510-1514 (1992)
C18	Colombo, "Swelling-controlled release in hydrogel matrices for oral route," Advanced Drug Delivery Reviews, 11, pp. 37-57 (1993)
C19	Daly et al., "The effect of anionic surfactants on the release of chlorpheniramine from a polymer matrix tablet," Int. J. Pharmaceutics, 18, pp. 201-205 (1984)
C20	El-Shanawany, "Sustained Release of Nitrofurantion From Inert Wax Matrixes", J. Controlled Release, 26(1) pp. 11-19, 1993
C21	English translation of Japanese text of J.L. White, Twin Screw Extrusion, Technology and Principles, pages 14 and 37, 1981
C22	Evrard et al., "Melt Granulation With a New Laboratory High-Shear Mixer", Laboratoire de Pharmacie Galenique, Institut de Pharmacie NO DATE AVAILABLE
C23	FDA Guide to Inspections of Oral Solid Dosage Forms Pre/Post Approval issues for Development and Validation, January 1994
C24	Flanders et al., "The Control of Drug Releases From Conventional Melt Granulation Matrices", Drug Dev. and Indust. Pharm., 13(6) pp. 1001-22, (1987)
C25	Follonier et al., "Evaluation of Hot-Melt Extrusion as a New Technique for the Production of Polymer-Based Pellets for Sustained Release Capsules containing high loadings of freely soluble drugs," Drug Development and Industrial Pharmacy, 20(8), 1323-1339 (1994)
C26	Follonier et al., "Hot-Melt Extruded Pellets for the Sustained Release of Highly Dosed Freely Soluble Drugs," Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 18, pp. 578-579 (1991)
C27	Follonier et al., "Various Ways of Modulating the Release of Diltiazem Hydrochloride from Hot-melt Extruded Sustained Release Pellets Prepared Using Polymeric Materials", J. Controlled Release, 36, pp. 243-250 (1995).
C28	Ford et al., "Formulation of sustained release promethazine hydrochloride tablets using hydroxypropyl-methylcellulose matrices," Int. J. Pharmaceutics, 24, pp. 327-338 (1985)
C29	Ford, "The Current Status of Solid Dispensions", Pharm. Acta Helv. 61, Nr. 3, pp. 69-88 (1986)
C30	"Formulating for Controlled Release with METHOCEL@Premium Cellulose Ethers," The Dow Chemical Company, 1989
C31	Gennaro, "Particle Phenomena and Coarse Dispersions", Remington's Pharmaceutical Sciences, 17 th Edition, 1985, p. 301
C32	Goodhart et al., "Design and Use of a Laboratory Extruder for Pharmaceutical Granulations," Journal of Pharm. Sci., 62(1), p. 133-136 (1973)
C33	Hogan, "Hydroxypropylmethylcellulose Sustained Release Technology," Drug Dev. & Ind. Pharmacy, 15 (6 & 7) pp. 975-99 (1989)
C34	Huber et al., "Utilization of Hydrophilic Gums for the Control of Drug Release from Tablit Formulations-I. Disintegration and Dissolution Behavior," J. Pharm. Sci., 55 (9), pp. 974-976 (1966)
C35	Hunt et al., "Comparison of the Pharmacokinetic Profiles of Two Oral Controlled-Release Morphine Formulations in Healthy Young Adults," Clin. Ther., 13(4), pp. 482-488 (1990)

C36	Jozwiakowski et al., "Characterization of a Hot-Melt Fluid Bed Coating Process for Fine Granules", Pharm. Research, 7(11), pp. 1119-24 (1990)
C37	Khan, "Recent Trends and Progress in Sustained or Controlled Oral Delivery of Some Water Soluble Drugs: Morphine salts Diltazem and Captopril", Drug Devl. and Industr. Pharm. Vol. 21(9), pp. 1037-1070 (1995)
C38	Kinget et al., "Preparation and Properties of Granulates Containing Solid Dispersions," Acta Phar. tech., 31(2), pp. 57-62 (1985)
C39	Lachman et al., "The Theory and Practice of Industrial Pharmacy", p. 315. Lea & Febiger, Phi. 1976
C40	Lin et al., "Biopharmaceutic Evaluation of Controlled-Release Hydrophilic-Matrix Tablets Containing Encapsulated or Unencapsulated Salbutamol, Sulfate," Current Therapeutic Research 52 (3) pp. 486-492 (1992)
C41	Longer, "Sustained-Release Drug Deliver Systems", Remington's Pharm. Scie., 18 th Edition, pp. 1676-1693, 1990.
C42	McCabe, "Twin Screw Extrusion in the Production of Novel Dosage Forms," Pharmaceutical Manufacturing Review (1994)
C43	McTaggart et al., "The Evaluation of Formulation and Processing Conditions of a Melt Granulation Process", Int'l. J. Pharm. 19(2) pp. 139-148 (1984)
C44	METHOCEL, Colorcon, Technical Information NO DATE AVAILABLE
C45	Nicolas et al., "Hot-Melt Extruded Pellets For The Sustained Release Of Highly Dosed Freely Soluble Drugs", Capsule News, Vol. 1, No. 3, Edited by Roland Daumesnil, (June/July 1991)
C46	Niskanen et al., "Pelletization in a Centrifugal Granulator, Part I: Effects of Binder-Solution Concentration", Pharm. Tech. Int'l., pp. 22-38 (1990)
C47	Publication, KEX, Twin Screw Compounding Extruder (October 1989)
C48	Rao et al., "Swelling controlled-release systems: recent developments and applications," Int. J. Pharmaceutics, 48, pp. 1-13 (1988)
C49	Royce et al., "Alternative Granulation Technique: Melt Granulation", Drug Dev. and Industr. Pharmacy, 22 (9 & 10), pp. 917-92 (1996)
C50	Schaefer et al., "Melt Granulation in a Laboratory Scale High Shear Mixer", Drug Dev. and Indust. Phar., 16(8) pp. 1249-1277 (1990)
C51	Schaefer et al., "Melt Pelletization in a High Shear Mixer I Effects of Process Variables and Binder", Acta Pharm. Nord. 4(3) pp. 133-140 (1992)
C52	Sekiguchi et al., "Studies on Absorption of Eutectic Mixture....", Chem. Pharm. Bull., 9 pp. 866-872 (1961)
C53	Skelly, "Scale-up of Immediate Release Oral Solid Dosage Forms, AAPS/FDA Workshop Committee, Pharmaceutical Technology, pp. 68-74, April 1995
C54	Sustained Release Medications, pp. 50-53, Noyes Data Corp. (J.C. Johnson). 1980
C55	Sy et al., "Current Therapeutic Research," 52(3), pp. 486-492 (1992)
C56	Thomsen et al., "Prolonged Release Matrix Pellets Prepared by melt Pelletization I. Process Variables", Drug Dev. and Industrial Pharm., 19(15) pp. 1867-1887 (1993)
C57	Thomsen, "Matrix Pellets Prolonged Formulations Prepared by Melt Pelletization", Dept of Pharm. royal Danish School of Pharmacy, 1992
C58	Thomsen, "Prolonged Release Matrix Pellets Prepared by melt Pelletization, Part IV: Drug Content, Drug Particle Size and Binder Composition", Pharmaceutical Technology Europa, pp. 19-22 (October 1994)
C59	Thomsen, "Utilizing melt pelletization technique for the preparation of prolonged release products", Pelletization, (material elaborated by assistant Prof. Lars Juul Thomsen, Dept. of Pharmaceutics, Royal Danish School of Pharmacy for the DIE course "Pelletization Technology", November 1992, 106 pages plus appendixes
C60	Van Bommei, "Production and Evaluation of In Vitro Release Characteristics of Spherical Gradient Matrix Systems", Acta Phar., Technol. 3b (2), pp. 74-78, 1990.
C61	Vazquez et al., "Influence of Technological Variables on Release of Drugs from Hydrophilic Matrices," Drug Dev. & Ind. Pharmacy, 18 (11 & 12), pp. 1355-1378 (1992)

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.